



MedStar Health

5565 Sterrett Place
5th Floor
Columbia, MD 21044
410-772-6500 **PHONE**
410-715-3754 **FAX**
medstarhealth.org

June 30, 2015

RECEIVED

Eileen Fleck
Chief, Specialized Services Policy and Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

JUN 30 2015

MARYLAND HEALTH
CARE COMMISSION

Re: June 18, 2015 Draft Amendments to State Health Plan (SHP) for Cardiac Services

Dear Ms. Fleck:

On behalf of MedStar Health, I am writing to provide the following comments regarding the June 18, 2015 draft amendments to the SHP for cardiac services. These comments are in addition to the comments we submitted on the first draft released on April 15, 2015.

First, we applaud the clarification regarding the types of cases for which the minimum volume standards apply contained in this draft. Volume standards for certificate of need purposes should be, and have always been, tied to open heart surgery and not to the broader category of "cardiac surgery." It is critical for quality purposes that providers perform a minimum volume of open heart surgery cases. Numerous studies have shown the strong link between volume and quality for open heart surgery. Use of the term cardiac surgery would have significantly reduced the numbers of open heart surgery cases necessary to operate a program and negatively affect the quality of care provided at those sites. And, artificially pumping up the volumes becomes particularly problematic when trying to accurately calculate community need.

It is important to note, the proposed plan already significantly reduces the *minimum* number of open heart cases necessary to obtain and maintain a CON for cardiac surgery. In fact, we had suggested previously that the plan should also include *optimal* volume standards that would take into account efficiency and financial viability.

Second, we are concerned that, for hospitals with all three of the types of cardiac programs (open heart, primary PCI, and elective PCI) the proposed regulations: 1) are unnecessarily complex and burdensome; 2) contain both duplicative requirements and varying compliance dates across all three programs; and 3) provide no alignment between the physician and hospital internal and external review requirements and there is no clarity on the review cycle.

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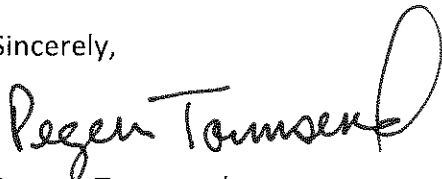
We recognize and appreciate the fact that much of the discussion surrounding this draft chapter was on developing an appropriate regulatory structure for hospitals to provide PCI services without open heart backup capability. There was little, if any, focus on how hospitals proving all three services would effectively operationalize meeting these requirements.

Please know, we are absolutely committed to meeting stringent quality oversight requirements, but ask that you consider the following suggestions to make compliance more straight forward and streamlined.

- Create a consolidated “certificate of ongoing performance” for hospitals providing all three types of cardiac services;
- Consolidate, streamline, and align the external and internal review requirements for physicians and hospitals;
- Annually publish the schedule for submission of “certificates of ongoing performance” for all categories of cardiac services in the Maryland Register;
- Further assess the information the MHCC already receives via hospital participation in the two national registries and work to reduce additional state reporting requirements; and
- Develop a schedule for submission of the initial applications for certificates of ongoing performance for existing programs and specify the frequency for renewals.

MedStar Health thanks you for the opportunity to comment on the June 18th Draft Amendments to State Health Plan for Cardiac Services. We look forward to working with you and others to ensure the successful adoption of a plan that will provide access to quality and cost effective cardiovascular services for the residents of Maryland.

Sincerely,

A handwritten signature in black ink, reading "Pegeen Townsend". The signature is fluid and cursive, with a large loop at the end of the last name.

Pegeen Townsend
Vice President, Government Affairs
MedStar Health